REMARKS/ARGUMENTS

Status of the Prosecution and Amendments Made Herein:

Claims 1-18 are pending and were examined in the July 25, 2003 Office Action. Claims 1-18 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Claims 1-18 also stand rejected under 35 U.S.C. §112, second paragraph, as allegedly incomplete due to the omission of essential steps. Claims 2 and 4 have been further rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness in the recitation of "portion" of a vanilloid receptor protein. Claims 1-3 and 6-16 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Szallasi *et al.* (Neuroscience Lett. 165: 101-104, 1994).

In accordance with the present amendment, claims 2-4 and 12 are canceled and claims 1, 8, 9, 13 and 15-17 have been amended. Support for the amended claims may be found throughout the specification, such that the amendments add no new matter to the application. Applicants submit that the currently amended claims are in condition for allowance. Support for Applicants' assertion is set forth below.

The Claims are Enabled by the Specification:

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. According to the Action, the specification does not enable practice of the subject matter of claims 1-18 in their full scope. First, the Action alleges that the specification enables a method utilizing the human VR1 vanilloid receptor, but no other vanilloid receptors. Without acknowledging the correctness of the examiner's position with respect to original claims 1-18,

the claims have been amended to recite a method that utilizes the human VR1 vanilloid receptor. Accordingly, the rejection on this ground should be withdrawn.

The Action also alleges that the specification does not enable a method utilizing "at least a ligand-interacting portion of a vanilloid receptor protein." Without acknowledging the correctness of the examiner's position with respect to original claims 1 and 3-16, those claims have been amended to remove the allegedly non-enabled recitation. Accordingly, the rejection on this ground should also be withdrawn.

The Action further alleges that the claimed method requires "the critical combination of hVR-1 and AGP at a pH of about 8.0 or greater, and additionally that 2 mM $MgCl_2$ and 0.75 mM $CaCl_2$ are required to practice the method with a reasonable expectation of success. Without acknowledging the correctness of the examiner's position with respect to the pH utilized in the method, the claims have been amended to call for a pH of between 8.0 and 10.0. Accordingly, the rejection on this ground should be withdrawn. Applicants traverse the remainder of the rejection.

With respect to the use of AGP in the method, Applicants assert that persons of ordinary skill in the art would know many ways of removing unbound ligand from a reaction mixture comprising a vanilloid receptor and a ligand. Thus, while the use of AGP is preferred in the present invention, it is not part of a "critical combination" comprising hVR1, AGP and pH 8.0 or greater. Further, one of skill in the art could easily determine the preferability of the method with or without AGP by conducting a simple and routine experiment, which certainly cannot be considered undue experimentation within the meaning of the statute.

Likewise, the inclusion of divalent cations such as $MgCl_2$ and $CaCl_2$ is explicitly stated in the instant application as preferred, but not required, to practice the claimed method. The fact that the references reviewed by the examiner disclose only methods that include these cations merely indicates that their use is preferred in the art, not that their use is required. Furthermore, as stated above, one of skill in the art could easily determine whether divalent cations improve the claimed method, simply by conducting an experiment in which the method is practiced with and without the cations. Again, this can hardly be considered undue experimentation as intended under the statute.

For the foregoing reasons, Applicants assert that the methods as recited in the currently amended claims are fully enabled by the specification. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is requested.

The Claims are Definite:

Claims 1-18 stand rejected under 35 U.S.C. §112, second paragraph as allegedly incomplete for failing to recite an essential step. According to the examiner, the step of "determining if the test compound bound to the receptor by observing a reduction in the amount of expected labeled ligand" is insufficient because it does not provide a point of reference from which to compare the "reduction." The claims have been amended to now recite a point of comparison for this step, such that the rejection on this ground should be overcome.

Claims 2 and 4 were further rejected as indefinite in the recitation of a "portion" of the vanilloid receptor. The claims have been amended to remove the allegedly indefinite recitation, such that the rejection on this ground also should be overcome.

Applicants assert that all amended claims are definite and particularly point out and distinctly claim the subject matter Applicants regard as their invention. Applicants therefore request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

The Claimed Subject Matter is Novel Over Szallasi *et al.*:

Claims 1-3 and 6-16 stand rejected under 35 U.S.C. §35 U.S.C. § 102(b) as allegedly anticipated by Szallasi *et al.* (Neuroscience Lett. 165: 101-104, 1994). Applicants traverse the rejection as it may be applied to the amended claims.

Proof of anticipation (i.e. prior knowledge by others) requires that all of the elements and limitations of the claimed subject matter must be described, expressly or inherently, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988).

The Office Action states that Szallasi et al. disclose a binding assay performed of a pH of "about 7.5," and including 2mM $MgCl_2$, 0.75 nM $CaCl_2$, AGP, labeled RTX, a test compound, a recovery step and a comparative step. However, Szallasi et al. do not disclose a method utilizing a pH of about 8.0 to about 10.0, as recited in the currently amended claims. Therefore, Szallasi *et al.* cannot be said to anticipate the invention as presently claimed. Applicants therefore request withdrawal of the rejection under 35 U.S.C. §102(b) on the basis of Szallasi *et al.*

Conclusion:

In view of the amendments submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicants respectfully request early and favorable reconsideration and withdrawal of the rejections set forth in the July 25, 2003 Official Action, and allowance of this application.

Respectfully submitted,

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